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EXAMINER	
PANI, JOHN	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,557	NIJSEN, MARIA JOHANNA MAGDALENA ALDINA	
	Examiner	Art Unit	
	John Pani	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 4, 6-10, 12-14, 16, and 19-20 are objected to because of the following informalities:

In reference to Claim 4

In line 2, it is suggested to replace "the duodenum" with –a duodenum--.

In reference to Claim 6

In line 3, it is suggested to replace "the test animal" with –a test animal--.

In reference to Claim 7

In line 2, it is suggested to insert --module-- between "sensor" and "comprises".

In reference to Claim 8

In line 2, it is suggested to insert --module-- between "sensor" and "is connected".

In reference to Claim 9

In line 4 it is suggested to replace "the tube end" with –a tube end--.

In reference to Claim 10

In line 4 it is suggested to replace "point" with –position--.

In reference to Claim 12

In line 6 it is suggested to insert –module—between "sensor" and "with an external".

In reference to Claim 13

In line 2 it is suggested to replace "the duodenum of the test animal" with --a duodenum of a test animal--.

In reference to Claim 14

In line 3 it is suggested to replace "the proximal end" with --a proximal end--.

In reference to Claim 16

In line 2 it is suggested to replace "the proximal" with –a proximal--.

In reference to Claims 19 and 20

In line 5 it is suggested to insert –module—between "sensor" and "with an external".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to Claims 1-8

The claims refer to "an animal model". It is unclear whether the animal model includes an animal as part of the limitations, thereby rendering the claim indefinite.

In reference to Claim 10

Line 2 recites that "the elastic material is also attached at the end of the biocompatible tubing". It is unclear whether this refers to a second end, separate from "the tube end" referred to in line 4 of claim 9, thereby rendering claim 10 indefinite.

In reference to Claim 11

In line 2, it is unclear whether "the tube end" refers to "the tube end" of claim 9, or "the end of the biocompatible tubing" of claim 10, or whether these ends are one and the same.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims refer to "an animal model", and it appears that by doing such they are claiming the actual test animal, in addition to various apparatuses implanted therein. The living matter (i.e. the animal) itself has not been the result of human intervention, and is thus not patentable (see MPEP § 2105 (R-1)).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,275,169 to Afromowitz et al. ("Afromowitz").

In reference to Claim 9

Aframowitz teaches a balloon catheter (see Fig. 3) comprising biocompatible tubing (**48**) closed at one end with elastic material characterized in that the elastic material (**52**) is attached to the biocompatible tubing at a position proximal from the tube end (see Fig. 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,275,169 to Afromowitz et al. ("Afromowitz") in view of US Pat. No. 6,491,663 to Lemelson ("Lemelson").

In reference to Claim 10

Afromowitz teaches the catheter of claim 9 (see above) wherein the elastic material is also attached at the end of the biocompatible tubing (see Fig. 3) further

comprising a number of holes distal from attachment point (see Fig. 3). However it is unclear whether the end is rigidly sealed. Lemelson teaches a balloon catheter that includes a rigid tip because this is desirable for implantation (see col. 5 lines 33-40). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Afromowitz by including a rigid distal tip in order to facilitate implantation as taught by Lemelson.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Afromowitz in view of US Pat. No. 4,405,313 to Sisley et al. ("Sisley").

In reference to Claim 11

Afromowitz teaches the catheter of claim 9 (see above) but does not explicitly disclose fixation means positioned proximal from the tube end. Sisley teaches an implantable catheter with proximal cuff positionable in order to fix the catheter after implantation (see col. 6 lines 59-63). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Afromowitz by including a fixation means such as the cuff of Sisley in order to fix the catheter to the subject after implantation.

10. Claim 1-2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Evidence that spinal 5-HT_1, 5-HT_2, and 5-HT_3 receptor subtypes modulate responses to noxious colorectal distension in the rat" to Danzebrink et al. ("Danzebrink") in view of US 2002/0024450 to Townsend et al. ("Townsend").

In reference to Claim 1

Danzebrink teaches an animal model for measuring visceral pain comprising a balloon catheter ("flexible balloon") and an implantable sensor module ("femoral arterial i.t. cathethers" and "electrodes for electromyographic recording") (see pg. 65). However, Danzebrink does not mention that the implantable sensors have transcutaneous telemetring ability. Townsend teaches an implantable data collection device which collects data from a variety of implanted sensors (including EMG, see [0039]) and blood pressure, see [0035]) and transmits the data transcutaneously (see [0030]). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Danzebrink by substituting the wireless device of Townsend for the wires used by Danzebrink to transmit the data from the EMG and blood pressure catheters in order to reduce wires extending from the animal thereby eliminating extraneous percutaneous sources of infection and snag hazards, as implicitly taught by Townsend.

In reference to Claim 2

Danzebrink in view of Townsend teaches the model of claim 1 (see above) and Danzebrink further teaches that the balloon catheter is an implantable balloon catheter (the balloon is inserted and maintained in the intestine).

In reference to Claim 4

Danzebrink in view of Townsend teaches the model of claim 2 (see above), and the balloon catheter of Danzebrink is capable of being implanted into the duodenum.

In reference to Claim 5

Danzebrink in view of Townsend teaches the model of claim 1 (see above) and Townsend further teaches that the implantable sensor module is capable of accepting a plurality of input signals (see [0033]).

In reference to Claim 6

Danzebrink in view of Townsend teaches the model of claim 5 (see above) and Townsend further teaches that the implantable sensor module is set up to receive both visceromotor (EMG) and pseudoaffective (blood pressure) responses of the test animal.

In reference to Claim 7

Danzebrink in view of Townsend teaches the model of claim 5 (see above) and Townsend teaches the implantable sensor module comprises at least two input ports (see [0033], "sensors" means at least two).

In reference to Claim 8

Danzebrink in view of Townsend teaches the model of claim 5 (see above), and Danzebrink further teaches that the sensors are a bipolar electrode pair and a blood catheter (see pg. 65, 4th paragraph).

11. Claims 3 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danzebrink in view of Townsend as applied to claim 2 above, and further in view of Sisley.

In reference to Claim 3

Danzebrink in view of Townsend teaches the model of claim 2 (see above) but does not teach that the catheter includes fixation means. Sisley teaches an implantable

catheter which includes a cuff for fixing the catheter in position (see col. 6 lines 59-63). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the system of Danzebrink by including a proximal cuff on the balloon catheter in order to hold it in place, as taught by Sisley.

In reference to Claim 18

Danzebrink in view of Townsend and Sisley teaches the model of claim 3 (see above) and further teaches that the fixation means comprises two nodes to fixate the catheter (the cuff of Sisley surrounds the catheter, and the opposite sides are each interpreted as nodes).

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Danzebrink in view of Townsend and Afromowitz.

In reference to Claim 12

Danzebrink teaches a method for measuring visceral pain comprising implanting a balloon catheter (see pg. 65, 2nd paragraph); implanting an implantable sensor module (pg. 65, 4th paragraph); and monitoring the signals from the implantable sensor with an external module (see Fig. 1); and processing the signals (pg. 65, 9th paragraph). However, Danzebrink does not teach that the balloon catheter is structured like that of claim 9, or that the sensor module has transcutaneous telemetering ability.

Afromowitz teaches the catheter of claim 9 (see above) and teaches that it is appropriate for determining physiologic characteristics of body lumens. It would have been obvious to one having ordinary skill in the art at the time of the invention to have

used the catheter of Afromowitz in the method of Danzebrink because it is useful in determining physiologic characteristics of body lumens, as taught by Afromowitz.

Townsend teaches an implantable data collection device which collects data from a variety of implanted sensors (including EMG, see [0039]) and blood pressure, see [0035]) and transmits the data transcutaneously (see [0030]). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Danzebrink by substituting the wireless device of Townsend for the wires used by Danzebrink to transmit the data from the EMG and blood pressure catheters in order to reduce wires extending from the animal thereby eliminating extraneous percutaneous sources of infection and snag hazards, as implicitly taught by Townsend.

13. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danzebrink in view of Townsend and Afromowitz as applied to claim 12 above, and further in view of "Mechanical visceral pain model: Chronic intermittent distention in the rat" to Colburn et al. ("Colburn").

In reference to Claim 13

Danzebrink in view of Townsend and Afromowitz teaches the method of claim 12 (see above) and Townsend teaches the implantable sensor module is set up to receive both visceromotor (EMG) and pseudoaffective (blood pressure) responses of the test animal. However, they do not teach that the balloon catheter is implanted in the duodenum of a test animal. Colburn teaches a method of measuring visceral pain in which the balloon catheter is implanted in the duodenum of a test animal (see pg. 191,

3rd paragraph), as this provides a useful model for visceral pain. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Danzebrink by implanting the balloon catheter in the duodenum, as taught by Colburn, as this provides a useful model for visceral pain, as taught by Colburn.

In reference to Claims 14 and 15

Danzebrink in view of Townsend and Afromowitz teach the method of claim 12 (see above) but do not mention introducing a measured volume of inflation medium through the proximal end of the balloon catheter using a syringe. Colburn teaches teaches introducing a measure volume of inflation medium through the proximal end of the balloon catheter (pg. 193, 4th paragraph) via a syringe. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Danzebrink by using a syringe to introduce a measured volume of inflation medium to the balloon, as taught by Colburn, in order to controllably inflate the balloon during distention.

In reference to Claims 16 and 17

Danzebrink in view of Townsend, Afromowitz and Colburn teaches the method of claim 13 (see above) and Colburn further teaches introducing a measure volume of inflation medium through the proximal end of the balloon catheter (pg. 193, 4th paragraph) via a syringe.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Danzebrink in view of Townsend and Afromowitz and further in view of Lemelson.

Danzebrink in view of Townsend and Afromowitz teaches the method of claim 19 (see rejection of claim 12) with the exception of specifying that the tubing is rigidly sealed. Lemelson teaches a balloon catheter that includes a rigid tip because this is desirable for implantation (see col. 5 lines 33-40). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Afromowitz by including a rigid distal tip in order to facilitate implantation as taught by Lemelson.

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Danzebrink in view of Townsend and Afromowitz, Lemelson, and Sisley.

Danzebrink in view of Townsend, Afromowitz, and Lemelson teaches the method of claim 20 (see rejection of claim 19) with the exception of fixation means proximal from the tube end. Sisley teaches an implantable catheter with proximal cuff positionable in order to fix the catheter after implantation (see col. 6 lines 59-63). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Afromowitz by including a fixation means such as the cuff of Sisley in order to fix the catheter to the subject after implantation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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